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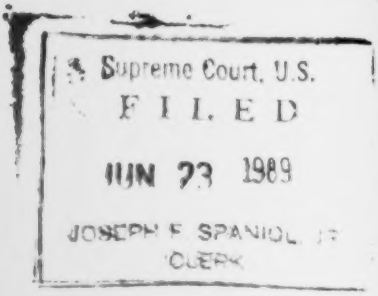

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

MEDICS PHARMACEUTICAL CORP., PETITIONER

vs.

CAROL LYNN NEWMAN

PETITION FOR A WRIT OF CERTIORARI

TO THE COURT OF APPEALS OF GEORGIA

Peter Joachim Krebs

1826 Clairmont Road

Decatur, GA 30033

(404)325-5910

Counsel of Record

QUESTIONS PRESENTED

1. Whether the judicial decision of the Court of Appeals of Georgia pertaining to the sale of diethylstilbesterol (DES) to respondent's mother in 1963 violated the equal protection clause of Amendment XIV to the Constitution.

2. Whether the due process requirements to private companies under Amendment XV to the Constitution were violated.

3. Whether said judicial decision violated the commerce clause of Article I, section 8, clause 3 of the Constitution of the United States.

4. Whether said judicial decision violated the contract clause of Article I, section 10, clause 1 of the Constitution of the United States.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

NO.

MEDICS PHARMACEUTICAL CORP.,PETITIONER

v.

CAROL LYNN NEWMAN

PETITION FOR A WRIT OF CERTIORARI TO

THE COURT OF APPEALS OF GEORGIA

The petitioner corporation is not affiliated with anyone.

OPINIONS BELOW

The opinion of the Court of Appeals of Georgia (App. B p.2a) is reported in 190 GA. App. 197. The judgment of the State trial court is not reported. (App.A p.1a).

JURISDICTION

The judgment of the Court of Appeals of Georgia was entered on January 24, 1989 (App. B infra p.2a). A petition for rehearing was denied on February 7, 1989 (App. C infra, p.10a). A petition for certiorari to the Supreme Court of Georgia was denied on March 8, 1989 (App. D infra p.11a) and a motion for rehearing of the denial of the petition for certiorari was denied on March 29, 1989 (App. E, infra p.12a).

The jurisdiction of this Court is invoked under 28 U.S.C. 1257(a).

CONSTITUTIONAL PROVISIONS AND STATUTORY PROVISIONS INVOLVED

Section I of Fourteenth Amendment to the Constitution provides:

> All persons born or naturalized in the United States and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Statutes:

21 U.S.C. 301 Federal Food, Drug and Cosmetic Act

Appendix G, page 15a.

Georgia Code Ann. Title 109A-2

Appendix H, page 18a.

STATEMENT OF THE CASE

This case was originally decided in the Superior Court of DeKalb County, GA on January 24, 1988. (App. A p.1a).

The Appeal to the Court of Appeals of Georgia was denied, (App.B p.2a) as was petitioner's motion for rehearing. (App. C p.10a).

The subsequent petition for certiorari to the Supreme Court of Georgia was denied, (App. D p.11a) as was petitioner's motion for rehearing of that denial, decided on March 29, 1989. (App. E p.12a). Petitioner has exhausted all its remedies in the State of Georgia. Timely notice of intention to apply to the United States Supreme Court was filed on April 14, 1989, with the Georgia Court of Appeals. (App. F p.13a). The case was commenced by the respondent Newman filing a Complaint

requesting damages for her injuries incurred due to the alleged ingestion by her mother of a drug product called Diastyl, claimed to have been sold to her mother by Oak Grove Pharmacy in a time period between December 17, 1963 and June 4, 1964. (R-230)

Petitioner's product Diastyl (diethylstilbesterol) was produced out of state, was shipped in interstate commerce to Georgia (R-69) and was subject to the regulations of the Federal and Drug Administration as these pertain also to label claims and warnings. (App G p.15a & 17a) Diastyl was received fully packaged, with instruction inserts contained in sealed stock packages. (R-60)

Labels and inserts gave the F.D.A. mandated indications for use and all required warnings and conditions of

use.(App. K p.25a)

Petitioner had warned all physicians of dangers and contra-indications that were known in 1963 i.e. at the time of Mrs. Newman's alleged purchase of Diastyl.

Evidence adduced during the proceedings of this case established that Louise Newman purchased some medication, allegedly prescribed by her physician for the prevention of miscarriage, from Oak Grove Pharmacy during 1963 and 1964. (R-230)

The Georgia statute in effect in 1963-64, at the time of the transaction, was Georgia Code Ann. 109A-2-314 and 109A-2-315 (Acts 1962, pp. 156-190) (App.H p.18a) and mandated that the ultimate seller, Oak Grove Pharmacy, was liable to the buyer, Louise Newman and not this petitioner.

There was a valid contract of sale between Oak Grove and Louise Newman, and Oak Grove Pharmacy was the proper party defendant and not the petitioner.

Georgia Ann. 109A-2-314 and Georgia Ann. 109A-2-315 further required that any applicable warranty arising out of contract for the sale of goods ran from the seller to the buyer in privity.

Other evidence submitted showed that in November, 1971, eight (8) years after the alleged sale, petitioner was advised by FDA of new warnings pertaining to DES and of contra-indications for use in pregnancy (App.I p.22a). The FDA letter sent to petitioner is part of the official records of the United States Food and Drug Administration (App. J p.23a).

Additional evidence adduced established

that the physician had been fully warned of all dangers of this prescription product, (R-353) and that the product was considered to be safe by FDA (R-77), (R-358) (T-413) (App I p.22a footnote).

Petitioner unsuccessfully moved the trial court to dismiss the petitioner as a defendant on the basis of the applicable statutory and case law. (R-46-R-85, also R-113-116, R-550-R-558) (T-204-208, T-218) also (T-313-315). No evidence was submitted to link petitioner's product with respondent's mother. (R-234)

The Court of Appeals refused to review these basic questions and dismissed eleven (11) enumerations of errors as being without merit (App. B p.2a). The questions sought to be presented are substantial Fourteenth Amendment

questions that are so substantial as to require plenary considerations with briefs on the merits and oral argument for their resolution.

REASONS FOR GRANTING THE WRIT

The failure of the Court of Appeals to consider the facts above, as set out in petitioner's enumerations of error, and its failure to reverse the trial court, resulted in an unbelievable miscarriage of justice.

Under the facts and under the law, the petitioner should have never been a defendant in this case, and on the basis of the other grounds, should never have been held liable to the respondent.

The separate clauses of the Fourteenth Amendment are a limitation on the states and its persuasive function is to exact from the states basic

observance of fundamental liberties. It is well settled that where violations of rights enumerated in the first ten amendments to the Federal Constitution exist, it amounts to a denial of due process of law, within the meaning of the Fourteenth Amendment, and conduct of that character by a state is forbidden and condemned by that Amendment.

Under the constitution, the Fourteenth Amendment guarantees everyone due process of law and equal protection under the law.The judicial decision of the State of Georgia ignores the Georgia statute in effect at the time of the sale, i.e. Georgia Code Ann. 109-2-314 and 109A-2-315. (App B p.2a), as well as the case law construing the statute. Mansfield Propane Gas Company et al v. Folger Gas Co. 231 Ga.App 861

Chaffin v. Atlanta Coca Cola Bottling Co., et al 127 Ga. App. 614.

Due process means due process according to the laws of a particular state, in this case that of the State of Georgia, State of Missouri v. Lewis, 101 U.S. 22, and the due process of law clause governs any action of a state, including the state's actions in judicial proceedings. Owens v. Battenfield, 280 U.S.605, 33 F. 2nd 753.

The petitioner is a person under Georgia Law and therefore entitled to the benefits of these constitutional guarantees, Frost v. Corporation Commission, 278 U.S. 515.

The action by the Court of Appeals of of Georgia dismissing the enumeration of errors brought up for appeal, deprives the petitioner of its

property, without due process of law, and deprives it of the equal protection of the laws and violates the Constitution, Louis K. Liggett Co. v. Baldridge, 278 U.S. 105, as the Court of Appeals acted expressly in the name of the state. United States v. Southerland 37 F Supp. 344.

The purpose of the due process provisions as they relate to judicial procedure is to insure fundamental fairness.

The due process clauses require further that a power conferred by law is to be exercised with the intent to fulfill the purpose of the law, and it is part of the judicial function that this requirement is met. Brinkerhoff-Faris Trust & Savings Co. v. Hill, 281 U.S. 673, 50 S. Ct. 451.

The petitioner's sale of drug products

in interstate commerce are covered by Title 21 United States Code, Food Drug & Cosmetic Act. (App G p.15a). The FDA has general authority in rule making and administrative enforcement, (App G p.17a) as discussed in U.S. v. Walsh, 331 U.S. 431. The federal Food Drug & Cosmetic Act is enforced by the Food and Drug Administration and provides to administrative officials the delegation of the congressional power to regulate interstate commerce. 21 USC 371.(App. G p.17a)

In the instant case, scientific and policy statements made by the Food and Drug Administration pertaining to diethylstilbesterol were communicated to the petitioner by the mailing of the F.D.A. letter in November 1971.(App I p.22a)

This letter required warnings to

physicians by drug companies marketing diehylstilbesterol that the drug was not to be given in pregnancy. (App I p.22a. The FDA letter is part of the administrative records of the Food and Drug Administration. (App J p.23a).

The courts have trusted the scientific decisions made by FDA and have accepted its policy choices. Weinberger v. Hynson, Westcott & Dunning, Inc. 412 US 609.

The Court of Appeals' failure to review the enumeration of errors pertaining to the FDA letter, which communicated the warnings of use in pregnant women, had the effect of violating the Fourteenth Amendment as it applies to the commerce clause of Article I, section 8 of the Constitution.

At all times, petitioner was subject to Food and Drug Administration

regulations, as is in the public interest to be so regulated, and its product met the requirements of the Federal Food Drug & Cosmetic Act. 21 U.S.C. 352(f) (App. G p.15a). Petitioner could not advocate uses that were not specifically allowed by FDA. 21 U.S.C. 352(n) (App. G p. 15a).

The evidence submitted showed also that the physician was adequately warned against untoward uses, side effects and contraindications as were known in 1963 and 1964 and the courts have held that if adequate warning was given to the learned intermediary, the physicians, the manufacturer of a drug was not liable to the patient/consumer. Stottlemire v. Cawood 213 F. Supp. 897, O'Hare v. Merck & Co., Inc., 381 F. 2nd 286, Webb v. Sandoz Chemical Works, 85 Ga. App. 405.

The Court of Appeals' citation of Burel v. Berlex Laboratories, Inc. No. (84-1624A, slip op. at 7 (N.D. Ga. 1986) is inapposite as it pertained to a motion for summary judgment made by a co-defendant to be dismissed as a party defendant who had manufactured DES since 1947 and had sold it to Berlex. This case was settled and dismissed.

Even though petitioner never advocated the use of Diastyl in pregnancy, it was absolutely impossible to warn physicians against the use in pregnancy in 1963 as petitioner was not advised until eight years later of any adverse uses in pregnancy.

For the Court of Appeals to render a judgment that the petitioner should have foreseen dangers in 1963 requires that the petitioner was able to predict the future.

CONCLUSION

This writ should be granted as the petitioner was not the proper party defendant under the law in effect at the time of transaction, and no evidence had been presented, showing that it was the petitioner's product that Mrs. Newman had ingested, and even if it had been petitioner's product, all warnings had been given to her physician which under the cited Federal decisions were sufficient to insulate petitioner from liability.

Respectfully submitted,
Peter Joachim Krebs
1826 Clairmont Road
Decatur, GA 30033
Counsel for Petitioner

APPENDIX A

CAROL LYNN NEWMAN

Plaintiff

vs. Civil Action

No. 82-7823

MEDICS PHARMACEUTICAL CORP.

Defendant

JUDGMENT

This action came on for trial on January 2, 1988, and after trial the jury returned a verdict for plaintiff in the sum of $811,692.50. The verdict, appearing proper as to form, the Court hereby,

ORDERS and ADJUDGES Defendant liable unto Plaintiff in the sum of $811,692.50, plus the costs of this action.

This 28th day of January, 1988.

(s) Jonathan Peters
Judge Jonathan Peters
DeKalb Sup.Ct.

APPENDIX B

Jan. 24, 1989

In the Court of Appeals of Georgia

77462. MEDICS PHARMACEUTICAL CORP.
v. NEWMAN. p-187
POPE, Judge.

Plaintiff Carol Lynn Newman was born June 23, 1964. During her pregnancy, Mrs. Newman's mother took a drug commonly known as DES. The drug was prescribed by Dr. Arthur A. Smith, an obstetrician, to prevent miscarriage. Dr. Smith testified he specifically prescribed Diastyl, a brand of DES marketed in the Atlanta area by defendant Medics Pharmaceutical Corporation. Defendant Medics did not

manufacture the drug but purchased it from a manufacturer with the brand name and Medics' corporate name on the label of each stock bottle. Medics marketed Diastyl to Dr. Smith and other physicians. Medics denied it ever promoted the drug for use in preventing miscarriage. The printed information included with each stock bottle, known as the "product insert", listed several indicated uses for Diastyl but did not mention use for prevention of miscarriage. Nevertheless, evidence was presented that DES was commonly prescribed by physicians for preventing miscarriage at the time plaintiff was born.

In the early 1970's a correlation was discovered between use of DES during pregnancy and subsequent development of genital cancer in the female offspring of mothers treated

with DES. In 1980, at the age of sixteen, defendant was diagnosed as having clear cell adenocarcinoma and underwent surgery for the removal of her uterus, cervix and vagina. Plaintiff brought an action against defendant to recover for her injuries. Although the original complaint alleged causes of action for negligence, strict liability and breach of warranty, the sole issue presented at trial was defendant's alleged negligence. Judgment was entered on the jury verdict awarding plaintiff $811,692.50 in damages. Defendant appeals.

1. Defendant contends the court erred in denying its motion for directed verdict because no evidence was presented by which defendant could be held liable to plaintiff in negligence. Defendant argues it cannot

be held liable for injuries arising out of the use of Diastyl to prevent miscarriages because it did not recommend or market its product for that purpose. However, evidence was presented from which the jury could conclude that defendant knew or should have known that physicians were regularly prescribing DES to prevent miscarriages. Whether a manufacturer or distributor of DES should have foreseen it would be used for preventing miscarriages is a question of fact for the jury. Burel v. Berlex Laboratories, Inc., No. C84-1624A, slip op. at 7 (N.D. Ga. 1986). "The maker of an article for sale or use by others must use reasonable care and skill in designing it . . . so that it is reasonably safe for the purposes for which it is intended, and for other

uses which are foreseeably probable . . . . (Emphasis supplied)" (Punctuation and citations omitted.) Ford Motor Co. v. Stubblefield, 171 Ga. App. 331, 335 (319 SE2d 470) (1984). Because a jury issue was presented as to the foreseeability of the drug's use to prevent miscarriages, a jury issue was also presented as to whether defendant used reasonable care in determining whether the drug was safe for that use.

During closing argument, plaintiff's attorney stated to the jury that plaintiff does not claim defendant "did anything wrong in failing to tell the doctors that it could cause cancer." Instead, plaintiff's attorney based his closing argument on the theory that defendant was negligent in failing to inform the medical profession that the drug was not

effective in preventing miscarriages. Dr. Smith testified that he was aware of studies questioning the efficacy of DES for preventing miscarriages but nevertheless prescribed the drug for that purpose because he had found it to be effective in his practice. Thus, defendant argues that its failure to warn the physician about the ineffectiveness of the drug was not the proximate cause of plaintiff's cancer. Defendant further argues that the statement by plaintiff's attorney in closing argument was an admission in judicio which would preclude plaintiff from recovering for defendant's failure to warn of the danger of cancer. Even if plaintiff were precluded from recovering for defendant's failure to warn of the specific, unknown danger of cancer, plaintiff was not precluded

from recovering for breach of the general duty of a manufacturer to use reasonable care to provide a product which is reasonably safe for those purposes for which it could foreseeably be used.

"Negligence has no precise legal meaning. Among the best has been declared to be 'the failure to observe, for the protection of the interests of another person, that degree of care, precaution, and vigilance which the circumstances justly demand, whereby such other person suffers injury.' (Cit.)" Ford Motor Co. v. Carter, 239 Ga. 657, 662 (238 SE2d 361)(1977). The issue raised by the evidence in this case was not whether defendant should have warned of a yet unknown danger but whether defendant used reasonable care and vigilance to discover whether any

dangers were posed by using the drug to prevent miscarriages.

Regardless of the theories argued by the attorneys to the jury, sufficient evidence was presented to submit the issue of defendant's negligence to the jury. Thus, the court did not err in denying defendant's motion for directed verdict.

2. We have considered defendant's remaining eleven enumerations of error and find them to be meritless.

Judgment affirmed. McMurray, P.J., and Benham, J., concur.

APPENDIX C

COURT OF APPEALS
of the STATE OF GEORGIA

Atlanta, February 7, 1989

The Honorable Court of Appeals met pursuant to adjournment.

The following order was passed:

77462. MEDICS PHARMACEUTICAL CORPORATION v. CAROL LYNN NEWMAN

Upon consideration of the motion for a rehearing filed in this case, it is ordered that it be hereby denied.

Court of Appeals of the State of Georgia
Clerk's Office, Atlanta Feb. 7, 1989

I certify that the above is a true extract from the minutes of the Court of Appeals of Georgia.

Witness my signature and the seal of said court hereto affixed the day and year last above written.

(s) Victoria McLaughlen
Clerk

APPENDIX D

CLERK'S OFFICE, SUPREME COURT OF GEORIA

Atlanta March 8, 1989

Case No. 46737, Medics Pharmaceutical Corporation v. Carol Lynn Newman C/A #77462.

The Supreme Court today denied the writ of certiorari in this case.

All the justices concu..

Very truly yours,
Joline B.Williams,
Clerk

APPENDIX E

Clerk's Office, Supreme Court of Georgia

Atlanta, March 29, 1989

The motion for a rehearing was denied today:

Case No. 46737 Medics Pharmaceutical Corp. v. Newman

Yours very truly,

Mrs. Joline B. Williams,
Clerk

APPENDIX F

IN THE COURT OF APPEALS

STATE OF GEORGIA

MEDICS PHARMACEUTICAL CORP.

Appellant

vs.

CAROL LYNN NEWMAN

Appellee

NOTICE OF INTENTION TO APPLY TO

THE UNITED STATES SUPREME COURT

FOR THE WRIT OF CERTIORARI

TO: CLERK, COURT OF APPEALS OF GEORGIA

You are hereby notified that pursuant to Rule 16(b), it is the intention of the Appellant to apply to the United States Supreme Court for the Writ of Certiorari to review the judgment of the Court of Appeals rendered and filed in the above-styled case on January 24, 1989 in which a Motion for Rehearing was denied by the Supreme Court of Georgia on March 29, 1989.

This 14th day of April, 1989.
Respectfully Submitted,

(s)Peter J. Krebs
Peter J. Krebs,
Bar #429450
Attorney for Appellant

KREBS AND ASSOCIATES, P.C.
1826 Clairmont Road
Decatur, Georgia 30030
404/325-5910

APPENDIX G

The Federal Food Drug and Cosmetic Act provides in pertinent parts:

1. 21 U.S.C. 301 - short title

   This chapter may be cited as the Federal Food, Drug and Cosmetic Act.

2. 21 U.S.C. 331 - prohibited acts

   The following acts and the causing thereof are prohibited:

   (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

3. 21 U.S.C. 352(f) - Directions for use and warnings on label

   (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous

to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users:

4. 21 U.S.C. 352(h) - Prescription drug advertisements; established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under subsection (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in

accordance with the procedure specified in section 371(e) of this title.

5. 21 U.S.C. 371(a) Regulations and hearings

Authority to promulgate regulations

a. The authority to promulgate regulations for the official enforcement of this chapter, except as provided in this section, is vested in the Secretary.

APPENDIX H

Ga. Code Ann. 109A-2-101

The pertinent portions of the Georgia Statute in effect in 1963 and 1964 are set out as follows:

109A-2-101. Short title. - This Article shall be known and may be cited as Uniform Commercial Code-Sales. (Acts 1962, pp. 156, 171.)

109-2-102. Scope; certain security and other transactions excluded from this Article. - Unless the context otherwise requires, this Article applies to transactions in goods.

109A-2-103. Definitions and index of definitions. - (a) In this Article unless the context otherwise requires

(a) "Buyer means a person who buys or contracts to buy goods.

(b) "Good faith" in the case of a merchant means honesty in fact

and the observance of reasonable commercial standards of fair dealing in the trade.

(c) "Receipt" of goods means taking physical possession of them.

(d) "Seller" means a person who sells or contracts to sell goods.

109A-2-314. Implied warranty: merchantability; usage of trade -

(1) Unless excluded or modified (109A-2-316), a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind. Under this section the serving for value of food or drink to be consumed either on the premises or elsewhere is a sale.

(2) Goods to be merchantable must be at least such as

(a) pass without objection in the trade under the contract description; and

(b) in the case of fungible goods, are of fair average quality within the description; and

(c) are fit for the ordinary purposes for which such goods are used; and

(d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and

(e) are adequately contained, packaged, and labeled as the agreement may require; and

(f) conform to the promises or affirmations of fact made on the container or label if any.

(3) Unless excluded or modified (109A-2-316) other implied warranties may arise from course of dealing or usage of trade. (Acts 1962, pp. 156, 189.)

109A-2-315. Implied warranty: fitness for particular purpose. - Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose. (Acts 1962, pp. 156, 190.)

APPENDIX I

November 1971

FDA

DRUG BULLETIN

DIETHYLSTILBESTROL CONTRAINDICATED IN PREGNANCY

APPENDIX J

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug

Administration

Rockville, MD 20857

AFFIDAVIT

Benjamin W. Carney, being first duly sworn, deposes and says:

1. I am the Deputy Director, Freedom of Information Staff, Office of the Associate Commissioner for Public Affairs, United States Food and Drug Administration.

2. In this capacity, I have custody of official records of the United States Food and Drug Administration.

3. Attached are copies of the following records maintained for public access by the Freedom of Information.

Staff concerning Diethylstilbestrol:

A. FDA Drug Bulletin dated November 1971.

B. FDA Drug Bulletin dated December 1985.

C. Copies of the administrative records are part of the official records of the United States Food and Drug Administration.

(s) Benjamin W. Carney
Benjamin W. Carney

County of Montgomery
State of Maryland

Subscribed and sworn to before me this twenty-second day of September 1987.

(s) Emma Rodas
Notary Public

My commission expires July 1, 1990.

APPENDIX K

Product Label

Front Panel:

Diastyl

(Diethylstilbesterol, 25 mg.)

MEDICS

Marketed by Medics Pharmaceutical Corporation

Decatur, Georgia, U.S.A.

Side Panel:

100 Tablets No. 302

Each tablet contains:

Diethylstilbesterol 25 mg

Dosage: Adults, one tablet daily, or as determined by physician.

INDICATIONS: Estrogen replacement therapy.

CONTRAINDICATIONS: History of familiar mammary or genital carcinoma. See brochure.

PRECAUTIONS AND SIDE EFFECTS: See

enclosed or attached brochure for complete side effects and precautions.

WARNING: This is an extremely dangerous and toxic drug, improper use may result in severe or fatal injury.

CAUTION: Federal Law prohibits dispensing without prescription.